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LASER PRODUCTS

Proposed Performance Standard

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[21 CFR Parts 1010 and 1040]

LASER PRODUCTS

Proposed Performance Standard

In the FEDERAL REGISTER of December 10, 1973 (38 FR 34084), the Commissioner of Food and Drugs proposed to amend Chapter I of Title 21 of the Code of Federal Regulations by adding to Subchapter J a new Part 1040, prescribing a performance standard for laser products in new §§ 1040.10 and 1040.11 (21 CFR 1040.10 and 1040.11). Sixty days were provided for public comment. Comments were received from two trade associations representing manufacturers of laser products; two industrial associations and one physics education association representing users of laser products; two voluntary safety standards organizations; a university medical research laboratory; an independent research institute; the Department of Labor; the Department of the Army; four State radiation control agencies; and numerous individual laser product manufacturers and users.

In response to these comments and to provide further clarification, the Commissioner has determined that a number of changes are necessary in the proposed performance standard which are sufficiently substantive to warrant republication as a proposed rule to provide an opportunity for public comment on these changes. In order to show how the proposed changes relate to the unchanged portions of the previous proposal, the entire text of the new proposal is published in this second notice of proposed rule making.

The comments received regarding the December 10, 1973, proposal and the Commissioner's analysis and proposed action are summarized as follows:

1. In reference to proposed § 1040.10 (b), several comments stated that clarification of the interconnected definitions of "laser," "laser energy source," and "laser product" is needed. Comments on the definition of "laser" stated that it failed to include both lasers emitting in the shorter ultraviolet wavelengths and lasers which do not require a separate laser energy source. Comments on the definition of "laser product" stated that the proposed rule did not make clear whether lasers sold to other manufacturers as replacement components were subject to the standard, nor did it clarify how "portions of the architectural structure" of an installation could be considered as part of a laser product.

The Commissioner concludes that the proposed definition of "laser" includes all lasers emitting at wavelengths which present a significant risk of human exposure and for which adequate measurement instrumentation is available. The definition of "laser" has been revised to clarify the relationship between a laser and a laser energy source.

The Commissioner also concludes that revision of the proposed definition of "laser product" is necessary to make clear that lasers sold to other manufacturers as original or replacement components would not be separately subject to the standard unless supplied directly to a product user. A laser product consisting of an assemblage of components installed by a person engaged in the business of such assembly still would be subject to the standard, with the assembler having the option of using portions of the installation's architectural structure to meet such requirements as that for a protective housing. However, the Commissioner concludes that the definition of "laser product" should be revised to eliminate the specific reference to architectural structures in order to avoid possible confusion.

The definition of "laser product" is further revised to make it more concise and to clarify that a product which is intended to incorporate a laser or laser system is subject to the standard even if it does not incorporate such laser or laser system at the time of manufacture or sale. The Commissioner believes that the definition must include such products in order to assure the effective implementation of the provisions of the standard, and to protect the public health and safety.

2. Several comments suggested adding to § 1040.10(b) definitions of certain terms whose meaning in the text was not clear or whose definition and usage would clarify general concepts in the standard. Other comments suggested deleting the definitions of terms which did not serve to convey an important specific meaning.

Accordingly, the Commissioner concludes that explicit definitions of the terms "operaton," "maintenance," "service," and "sampling interval" should be added and that the definitions of "pulse interval" and "maximum emission duration" should be deleted along with deleting all references to maximum emission duration, thus providing the clarification suggested by the comments.

3. The classification provisions of § 1040.10(c) establish laser product classification upon a graded risk to public health and safety from accessible laser radiation. Comments were received expressing satisfaction with the consistency of the classifications with those promulgated by the American National Standards Institute (ANSI). This consistency is a result of substantial cooperation and exchange of concepts between the ANSI Z–136 Committee on the Safe Use of Lasers and the Food and Drug Administration during the development of the ANSI Standard for the Safe Use of Lasers. Other comments were received that indicated a desire for inclusion of the method and results of the risk analysis conducted by the ANSI Z–136 Committee as the biological basis for the graded risk system presented in the first proposed rule.

The Commissioner concludes that in arriving at the upper limit for any given class, the minimal values for injury production reported in the scientific and technical literature were considered by the Food and Drug Administration in the belief that such values provide a more suitable representation of probabilities of damage. Although ANSI used a different method of analysis in deriving exposure limits, the ANSI exposure limits are consistent with the accessible emission limits for products prescribed in the FDA proposed standard.

4. Several of the comments objected to the use of data obtained from experiments with animals instead of human experimental data. One of the comments considered the use of such data invalid because of the lack of results which indicate that levels that produce minimal lesions in monkeys will produce injuries in humans. Another comment stated that the anesthetized and dilated monkey eye is not valid as a surrogate human eye.

The Commissioner believes that, in the absence of data which directly relate animal data to possible human effects, it is appropriate in the interest of public health to utilize the probabilities of damage obtained from animal research in estimating the risks to man. In the immobilized, anesthetized state there is motion of the eye of the monkey of a magnitude equivalent to the motion of the human eye when fixated upon an object. Dilation of the monkey pupil does correspond to the expected worst case in humans. The monkey eye thus appears to be a valid surrogate for the human eye. From a public health and safety viewpoint, the Commissioner reiterates that the data obtained from experiments performed on monkeys must be utilized in estimating human risks.

5. Several comments addressed the need for a biological basis that is supported by instances of human injury. According to the comments, no restrictions should be imposed on laser products in the absence of such support. The comments referred to situations in which human exposure occurred, but no injury was reported.

The Commissioner believes that the cited lack of damage in humans does not constitute documentation that damage could not have occurred, as concluded by the comments, but only that evidence of acute damage was not observed. Consideration of animal data presently available indicates that there are significant risks of injury to justify the classification scheme in the proposed performance standard for laser products. A significant potential for human injury is a sufficient basis for action to protect the public health and safety.

6. One comment stated that a new Class V for enclosed laser products should be added to the proposed standard to correspond to the Class V in the American National Standards Institute

(ANSI) Z-136.1-1973 Standard for the Safe Use of Lasers.

The Commissioner believes that an enclosed product is "enclosed" only to the extent that human access to laser radiation is prevented. A high-power laser in an enclosure could allow access to levels consistent with Class I, II or III as required by the function of the product. Thus, a separate Class V for "enclosed" products is unnecessary.

7. One comment stated that the term "spatially resolved" used in § 1040.10(c)(1) of the original proposed rule to distinguish between separate beams of laser radiation has a specialized meaning in the field of optics and that the term as used in the proposed standard should be clarified.

Because the specialized meaning which the comment attributed to the term "spatially resolved" is not consistent with the intended meaning in the original proposed rule, the Commissioner has decided to delete the original § 1040.10(c)(1) from the revised proposal and to distinguish operationally between those beams of laser radiation which can be treated separately in determining their hazard by means of the revised definition of "laser radiation" in § 1040.10(b) and the measurement provisions in § 1040.10(e)(3).

8. Several comments stated that Table I in § 1040.10(d) needs to be reorganized and clarified. Several additional comments indicated confusion over the meaning of the term "emission duration" in the text of the proposed standard and the use of the variable (t) in Table I. Throughout many of the comments, there was a common question concerning the mechanism for evaluating emissions from laser products which emit repetitively pulsed radiations.

The Commissioner accepts these comments. Table I has been divided into Tables I-A, I-B and I-C. They are more easily understood in this format. The revised format has allowed deletion of inapplicable and redundant portions. To remove an ambiguity between peak and average values, the accessible emission limits expressed in terms of radiant power, irradiance and source radiance have been expressed as the equivalent time-dependent functions of radiant energy, radiant exposure and integrated radiance. "Emission duration" has been redefined as a general term used to describe the accessible emission from a laser product. The emission duration of radiation is divided, as indicated in Tables I-A, I-B, and I-C, into several emission duration intervals. Each emission duration interval can be subdivided into a number of sampling intervals represented by the variable (t). A "sampling interval" is defined as the magnitude of the time during which the level of accessible laser or collateral radiation is determined by a measurement process. The determination of the level of accessible radiation need not necessarily be made over the entire sampling interval, if the measurement and an appropriate extrapolation procedure would yield an equivalent result.

The question concerning repetitively pulsed radiation has been clarified by redefining "emission duration" and distinguishing it from "sampling interval" and by the reorganization of units in Tables I-A, I-B, and I-C. Furthermore, the Class III accessible emission limits and emission duration intervals in Table I for laser radiation in the ultraviolet wavelengths have been revised in the new Table I-C to eliminate an unintended discontinuity in the emission limits for a sampling interval at the boundary between the originally proposed emission duration intervals.

9. Two comments requested deletion of the accessible emission limits for collateral radiation specified in Table III, Part A. These comments were predicated upon the belief that inclusion of such limits in the standard may be construed by some to imply that certain conventional light sources are unsuitable in general lighting applications.

The Commissioner intends that the purpose of setting limits for collateral radiation is to reduce unnecessary hazardous radiations arising from the operation of laser products. The Commissioner therefore concludes that Table III, Part A (referred to in this proposal as Table III, item 1), appropriately applies to laser products and should remain in the proposed standard.

10. Many comments concerning measurement requirements in § 1040.10(e)(2) were received. Several of these objected to requiring that the accessible emission level be the sum of the measured quantity of radiation and the cumulative measurement error, while some also objected to including the maximum expected increase in the measured quantity of radiation at any time after manufacture. One comment suggested use of the manufacturer's mean measured value as the accessible emission level for Class II laser products rather than the value for each laser product. Another comment suggested that measurement instruments should be required to be manufactured and certified in conformity with standards of the National Bureau of Standards (NBS) or other Federal agencies or with national consensus standards.

The Commissioner agrees that it may be confusing to express the accessible emission level as the sum of the measured emission, the cumulative measurement error and the maximum expected increase in the measured quantity of radiation at any time after manufacture. However, since the manufacturer must assure that each product which he certifies does not exceed the accessible emission limits applicable to that product at any time after manufacture, his tests and testing program for certification must take into account the measurement uncertainty as well as increases in emission and degradation of the product with age. Failure to do so could result in some products emitting above the limits upon which certification was based or otherwise failing to comply with the standard. The proposed standard has been revised to include these considerations and to clarify the intent of the Food and Drug Administration. The suggestion concerning use of the mean value of emissions for Class II laser products is rejected since the emission limits are intended to assure that no product exceeds them regardless of whether the mean emission of all such products is within those limits.

While the Commissioner agrees that it would be desirable for measurement instruments to be manufactured and certified to meet an appropriate NBS, other Federal, or national concensus standard, no adequate certification mechanism exists at this time. However, the comment has prompted a review of the need for specification of maximum allowable measurement error. The Commissioner concludes that a maximum measurement uncertainty of ± 20 percent for measurement systems may not always be obtainable and, in certain cases, may not be necessary to assure full compliance with the standard. Therefore, in order to provide a greater degree of flexibility in making measurements for compliance, the requirement for a maximum measurement uncertainty of ± 20 percent is deleted from the proposed standard, and appropriate guidelines will be issued by FDA to assist manufacturers in making compliance measurements.

11. In reference to the original § 1040.10(e)(1) concerning measurement conditions, one comment suggested that only controls and adjustments specified in user manuals should be required to be maximized during testing.

Since a laser product could be improperly adjusted by both the user and service personnel, the Commissioner concludes that the product must comply with the standard even when service controls are improperly adjusted. However, to clarify the original intent, the proposal has been revised to require maximizing the accessible emission levels by adjustment of maintenance controls as well as operation and service controls, whenever measurements are made to determine compliance.

12. For purposes of standardizing terminology, one comment requested that measurement of certain beam parameters, such as beam diameter, convergence and divergence, be included in the regulation.

While the Commissioner realizes that these parameters are of academic and engineering interest, he concludes that standardization of these terms is not necessary to protect the public health and safety.

13. Another comment suggested that all radiation measurements be made at a single fixed distance from the laser product which would then be defined as the point of closest human access.

The Commissioner believes that such an approach is not feasible for the wide variety of laser products to be regulated by the standard. However, to clarify further the method of determining human access, the Commissioner has revised the definition of "human access" to specify test objects more appropriate for determining the potential for access to radiation from the wide variety of laser products.

14. Two comments were directed toward the measurement provision in § 1040.10(e)(3)(i) requiring use of an 80-millimeter aperture stop to measure radiant power or energy. One comment requested guidance for preferred procedures of collecting radiation within the 80-millimeter diameter field. The other comment argued that the use of an 80-millimeter aperture stop in the measurement should be required only for those laser products intended to be used in conjunction with optical viewing aids.

The Commissioner concludes that it is more appropriate to supply detailed measurement guidelines after publication of the final rule. The Commissioner also concludes that a manufacturer does not know, and cannot be expected to know, the actual conditions under which a product is used. It is thus reasonable to assume that viewing of the beam with optical aids will occasionally occur either accidentally or intentionally. Thus, the requirement of an 80-millimeter aperture stop pursuant to § 1040.10(e)(3)(i) is both warranted and necessary in the interest of protecting the public health and safety.

15. One comment stated that the requirement for a protective housing in § 1040.10(f)(1) should apply only to laser systems rather than to all laser products because a laser by itself cannot radiate without a laser energy source and, therefore, does not need a protective housing to prevent unnecessary human access to radiation.

Because many lasers are designed to be operated simply by connection to a compatible laser energy source without further incorporation into a product housing, the Commissioner concludes that each laser and laser system which is not sold to another manufacturer as a product component should itself meet the requirement for a protective housing, which in many instances could be satisfied by the external surfaces of existing laser products.

16. Several comments contended that the safety interlock requirements in § 1040.10(f)(2) of the proposed standard are unduly burdensome and that greater flexibility should be provided by permitting alternate types of interlock systems such as the dual interlock system required by the performance standard for microwave ovens in § 1030.10(c)(2) (21 CFR 1030.10(c)(2)), but without interlock concealment and monitoring.

The Commissioner concludes that the proposed safety interlock requirements, while conceptually different from those in the microwave oven standard, would provide sufficient flexibility by requiring only one monitored safety interlock for each removable portion of the protective housing. Each such interlock can consist of either a simple interlock with an independent monitor or a single fail-safe mechanism combining both the interlock and monitor. Furthermore, such interlocks do not have to be electrical but can be mechanical. The safety interlock requirement also has been revised to prevent, upon housing displacement, access to those levels of radiation to which access must be prevented by the protective housing during operation.

17. Several comments stated that the requirements for remote control connectors, key-actuated master controls, emission indicators, and beam attenuators in § 1040.10(f)(3), (4), (5), and (6) should be imposed only on Class IV laser systems, or, at most, include in addition only those Class III laser products which emit invisible radiation or exceed a visible emission of 5 milliwatts.

The Commissioner concludes that a remote control connector and a key-actuated master control are needed on all Class III and IV laser systems to permit remote control of an acute radiation hazard and to prevent unauthorized operation, particularly in the more open areas, such as construction sites, in which products emitting visible radiation up to 5 milliwatts are used. The Commissioner also concludes that an emission indicator and beam attenuator are needed on all Class II, III, and IV laser systems to alert the user to the hazardous radiation before accidental exposure and to permit reliable reduction of the radiation hazard during routine alignment and adjustment procedures when it is not feasible to stop the generation of radiation. In particular, a visible beam would not adequately meet the requirements for an emission indicator because it would not always be visible through protective eyewear and would not warn of the hazard prior to possible exposure. The requirement that the remote control connector be only a two-terminal connector has been revised to permit the use of any electrical connector. The requirement for a beam attenuator also has been revised for clarification and flexibility. The requirement in § 1040.10(f)(6) for only a mechanical means of attenuation has been deleted, thus allowing alternative means of attenuation.

18. Some comments stated that the requirements pertaining to viewing optics should be revised to allow transmission of laser radiation at levels equal to the ambient light intensity and should not apply during servicing of the laser product.

The Commissioner concludes that unknown ambient light levels in the user environment cannot be considered in prescribing product performance requirements and that viewing optics should not, under any circumstances, transmit levels of radiation which present a hazard from chronic viewing, whether during operation, maintenance, or servicing.

19. There were several general comments on the labeling requirements in § 1040.10(g), including statements that label proportions and minimum label and lettering sizes should be specified, that the laser hazard symbol should be required on all labels, and that manufacturers could not position all labels on laser products to "preclude" human access to hazardous radiation during reading of such labels.

The Commissioner concludes that it is not feasible to specify label proportions and minimum dimensions which would be appropriate for all of the great variety of laser products subject to the standard and, accordingly, has revised the label specifications pertaining to the minimum size product to which required labels must be affixed by deleting the fixed area specification of 25 square centimeters and providing for a product-by-product determination of feasibility. It is also concluded that the use of the laser hazard symbol on all labels could cause confusion with the primary hazard warning which the warning logotypes are intended to convey. However, to permit additional flexibility, the warning logotype requirements of § 1040.10(g) have been revised to permit separation of the certification statement required by § 1010.2 (21 CFR 1010.2) from the warning logotype; and the label positioning requirement has been revised to require that labels be positioned to make access to radiation unnecessary during reading and that they be visible during operation, maintenance, and service.

20. Several comments stated that the specialized warning, "LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW WITH OPTICAL INSTRUMENTS", in § 1040.10(g)(3)(i) of the original proposal, could be misconstrued as warning against methods of viewing which would not be hazardous, such as off-axis viewing. Another comment stated that an aperture warning label should be required only for those apertures through which laser or collateral radiation in excess of the emission limits of Class I and Table III is emitted.

The Commissioner agrees that off-axis viewing would not be hazardous and concludes that the cited warning should be revised to warn only against viewing a beam directly with optical instruments, and that the aperture label requirement should be revised to warn against the emission of both laser and collateral radiation which is in excess of the emission limits of Class I or Table III.

21. One comment stated that protective housing labels should not be required for defeatably interlocked portions of the protective housing since an indicator is required by § 1040.10(f)(2)-(ii) to show when the interlock is defeated and access to radiation is permitted. The comment further stated that

such labels, if required, should warn only of a hazard upon interlock defeat and that manufacturers should be permitted to place all protective housing warning labels inside the protective housing unless radiation would exit from the product upon removal of such housing. It was also suggested that a further distinction be made on the required protective housing labels between levels of accessible visible laser radiation above 5 milliwatts and 2.5 milliwatts per square centimeter and levels below these values, and that the collateral radiation warnings be clarified to indicate that a hazard exists only when the housing is opened.

The Commissioner concludes that warning labels are needed on defeatably interlocked portions of the protective housing because the required defeat indicator merely alerts the user that the interlock is defeated but does not warn of the nature or degree of the radiation hazard. The Commissioner agrees that all protective housing labels should clearly indicate that a hazard exists when the housing is opened with any associated interlock defeated, but believes that protective housing warning labels should always be visible before removal of the housing. Additionally, as stated in the comments, since radiation might not be emitted from an opening created by removal of the housing but human access to radiation would still be possible, the Commissioner concludes that the protective housing labels should also be visible after removal of the protective housing. The Commissioner also agrees that the specific warnings should be revised to make the suggested additional distinction between accessible levels of visible laser radiation.

22. Several comments stated that manufacturers should not be required, as proposed in § 1040.10(h), to provide service instructions at cost to anyone without "legitimate need" because it was contended that FDA does not have authority to regulate the price charged for such instructions and that such a requirement might compel the release of proprietary information.

The Commissioner concludes that FDA has the authority to assure that radiation safety information is readily available and that this availability is not frustrated by a prohibitive cost. The Commissioner also concludes that radiation safety information relating to a product can and should be provided without necessitating the release of proprietary information. The radiation safety information that is required to be distributed to users has also been clarified by deleting the requirement that the method of measuring maximum output be specified and by adding the requirement that the maximum value shall include the measurement uncertainties and expected increases in the measured quantities at any time after manufacture.

23. A general comment on § 1040.11 concerning special use-group requirements suggested that any laser system used in an environment controlled by or subject to the authority of other Federal or State agencies which have established safe use programs for laser products should be exempted from the special use-group (specific purpose laser products) requirements.

The Commissioner believes that use of such products in a controlled environment does not negate the need for performance standards. The intent of the specific purpose laser product requirements, which incorporate unique product safety features, is to complement rather than supplant other safety requirements controlling the use of the laser product.

24. With respect to § 1040.11(a)(1) concerning medical laser products, one letter noted that the measurement accuracy requirement should not be more restrictive than that established for other laser products, and further stressed the need for reliability or repeatability of output rather than accuracy.

The Commissioner concludes that the intent of the measurement requirement is to insure accurate knowledge of the radiant power or energy which is intended for irradiation of patients. Without such knowledge, day-to-day reproducibility in patient irradiations would not be possible. However, based upon evaluations conducted by the Food and Drug Administration, the Commissioner agrees that the requirement for a ± 10 percent measurement accuracy could present technological difficulty and is overly restrictive. The Commissioner concludes that a measurement accuracy of ± 20 percent is sufficient to protect the public health and assess adequately the radiation levels intentionally applied to humans.

25. One comment questioned the necessity and practicality of a preset emission level for medical laser products. The comment noted that such a system could not compensate for unpredictable factors such as dust on optical components, mirror degradation, etc., and that extra adjustments would have to be made to regain the preset value after such perturbations have occurred.

The Commissioner concludes that the usefulness of a preset level could be offset by difficulties encountered in operation such as the perturbations mentioned. In addition, and more importantly, many new types of medical laser products are now being developed for which this requirement may not be appropriate. Therefore, the originally proposed § 1040.11(a)(2) has been deleted. The FDA will continue to explore the need for additional special requirements on medical laser products. Present needs which were identified and addressed in the revised proposal include the addition of products intended for surgical procedures to the definition of medical laser products and the requirement of an aperture label for laser and collateral radiation on medical laser products.

26. Concerning other special use-group requirements in § 1040.11(b) and (c), one comment suggested that maximum emission limits might be more effectively included in "use controls" or in "user standards" now being developed by various State and Federal agencies working with the assistance of the FDA.

The FDA is in active communication with other Federal agencies in an effort to ascertain the nature and extent of regulatory programs which are or will be implemented by those agencies. When a laser product is clearly intended only for uses controlled by another Federal or State agency, and when protection of the public health and safety is assured, FDA will reconsider the need for special performance requirements on the product. The Commissioner believes that any such user standards must provide equivalent protection for the health and safety of the public.

27. In reference to the maximum emission limits imposed on surveying, leveling, and alignment laser products by § 1040.11(b), several comments, to which extensive documentation and testimonials were attached, strongly stressed that an irradiance limit of 2.5 milliwatts per square centimeter is too low to allow sufficient power density for adequate performance of these laser products under conditions of high ambient illumination.

The Commissioner does not intend to preclude useful applications of laser products, but, instead, acknowledges that the use of potentially hazardous products is necessary to perform certain functions. The Commissioner agrees that adequate performance of surveying, leveling, and alignment laser products in high ambient light environments could be inhibited by the irradiance limit of 2.5 milliwatts per square centimeter. Above this level, however, there does exist a risk of acute injury to the eye should exposure occur. While the use of such products with known risks may be necessary, the use of hazardous radiation levels in excess of the ranges appropriate for the intended function cannot, under any rationale, be supported or condoned.

The Commissioner believes that, within the constraints of placing a limit on the total useful power, the other beam parameters for these special purposes are and will continue to be determined by the requirements for a particular application. The constraint of total useful power, together with lifetime variations in product output and quality control acceptance limits in the manufacturing process, define the upper limit of necessary hazardous radiation from such products. The data submitted on surveying, leveling, and alignment laser products indicate a need under high ambient illumination for 2 or 3 milliwatts of radiated power, but are not entirely clear concerning the utility of various levels of irradiance (power density). Many comments support the need for an emergent beam diameter of 8 to 10 millimeters, which would exceed the proposed irradiance limit with the cited optimum radiant

power because of the relatively small beam diameter. Furthermore, FDA is aware that many of these products are not presently equipped to provide even this large a beam diameter nor, from the data submitted, would any useful purpose be served by requiring all products to have expanded beams.

For all of the reasons listed above, the irradiance limitation, but not the power limitation for surveying, leveling, and alignment laser products has been deleted from § 1040.11(b). In so doing, the FDA recognizes the necessity for useful but not excessive beam powers. However, any Class III laser product which exceeds an irradiance of 2.5×10^{-3} watts per square centimeter must be clearly labeled as dangerous pursuant to § 1040.10(g)(2).

28. Additional comments on § 1040.11(b) suggested either increasing the accessible power limit for Class II laser products from 1.0×10^{-3} watts to 2.5×10^{-3} watts, or deleting the irradiance limit for surveying products entirely. It was also suggested that laser products for distance measurement also should be made subject to the requirements of § 1040.11(b).

The increase in Class II accessible emission limits is not supported by the available biological data. An increase in the limit is therefore not acceptable to the FDA. As noted above, the irradiance limit has been deleted. Imposition of the requirements of § 1040.11(b) on distance measurement laser products is not appropriate since substantially higher powers and different beam configurations are required for ranging purposes. The FDA will continue to explore the need for imposing special requirements on such products beyond the general requirements of the proposed standard.

29. An additional comment on the same provisions expressed the opinion that, a limitation on power or irradiance will only encourage a potential user to violate the law by purchasing a more powerful laser and adapting it for surveying, leveling, or alignment purposes.

The Commissioner believes that the revised requirements permit the manufacture of specific purpose laser products capable of performing any surveying, leveling or alignment function, and that it should not be necessary for a user to adapt a laser product not intended for such purpose. Furthermore, the use of any type of laser product in construction work is subject to radiation safety regulations promulgated by the Occupational Safety and Health Administration in 29 CFR 1926.54, as well as to some State regulations.

30. Section 1040.11(c) was commented upon at length by an organization representing physics teachers as well as by manufacturers of demonstration laser products. A question was raised concerning the meaning of the term "demonstration laser product" and what circumstances justify special requirements for these products. The human blink reflex, it was stated, would largely eliminate the acute risk of exposure to lasers emitting visible radiation up to 5 milliwatts. It was further stated that, with the risk eliminated by this reaction mechanism, such risk need not be included in the graded risk concept of classification.

The Commissioner concludes that the definition of "demonstration laser product" is sufficiently clear. The intent of the language is to cover only those products manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. It does not include laser products intended for research or for other non-demonstration purposes, provided the product is not also intended to be a "demonstration laser product." The intent of the manufacturer can be determined by a variety of manifestations and is not limited to the content of the manufacturer's advertisements. Furthermore, the proposed performance standard in no way prohibits the purchase and use of any laser product for any purpose.

Concerning the justification for the proposed special requirements for demonstration laser products, the Commissioner concludes that there are sufficient animal data to indicate a definite hazard at the radiation levels in question. In addition, a field study conducted by FDA revealed that lasers are being used in demonstrations in ways which could cause unintended exposure of students. The Commissioner recognizes the educational value of demonstration laser products and does not intend to prohibit their continued use in a classroom environment. However, it has been concluded that a definite hazard to both students and instructors can exist in the classroom situation and appropriate safety features must be incorporated in the product. The Commissioner does not agree that the blink reflex constitutes a reliable safety factor since the literature shows that a blink did not occur in a majority of human subjects tested for response to a light stimulus. Even under those circumstances where a blink can be elicited, an individual can override the reflex so that its potential utility would be negated.

31. Three letters suggested that a new § 1040.11(d) be established to encompass visible output helium neon lasers which are contained in products designed for nonchronic viewing. It was suggested that such a product should be Class I if its radiation emission did not exceed a radiant power of 39 microwatts or a radiance of 2×10^{-3} watts per square centimeter per steradian because viewing for more than 100 seconds is unlikely.

The Commissioner has concluded that the manufacturer cannot know the specific purposes for which a laser product will be employed by each user. Thus, the manufacturer cannot know that a laser not intended for chronic viewing would not be so viewed. It is, therefore, necessary to provide a warning on any product not suitable for chronic viewing that it should not be so viewed. Such a warning against the chronic exposure hazard from low-powered visible lasers is required for Class II laser products.

In addition to the changes discussed above, a number of editorial changes have been made in the proposed §§ 1040.10 and 1040.11 for internal consistency and clarity. Changes are also proposed in the general provisions of Part 1010 on performance standards to extend their applicability to the New Part 1040. As presently worded, Part 1010 does not refer to the new Part 1040.

Pertinent background data and information supporting the Commissioner's conclusions with respect to this proposal are available for public review in the office of the Hearing Clerk, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, pursuant to provisions of the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179; 42 U.S.C. 263f) and under authority delegated (21 CFR 2.120), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

1. By revising § 1010.1 to read as follows:

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

2. By revising paragraphs (a) and (c) of § 1010.2 to read as follows:

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.

* * * * *

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Secretary may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product ra-

diation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.

* * * * *

3. By revising introductory portion of paragraph (a) and paragraph (c) of § 1010.3 to read as follows:

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard.

* * * * *

(c) Every manufacturer of an electronic product to which is applicable a standard under this subchapter shall provide the Secretary with a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

4. By revising § 1010.13 to read as follows:

§ 1010.13 Special test procedures.

The Secretary may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standards under this subchapter for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

5. By revising § 1010.20 to read as follows:

§ 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

6. By adding a new Part 1040 to read as follows:

PART 1040—PERFORMANCE STANDARDS FOR LIGHT EMITTING PRODUCTS

Sec.
1040.10 Laser products.
1040.11 Specific purpose laser products.

AUTHORITY: Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f).

§ 1040.10 Laser products.

(a) *Applicability.* The provisions of this section and § 1040.11 are applicable as specified herein to all laser products manufactured or assembled on or after (one year after the date the final order is published in the FEDERAL REGISTER).

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) "Accessible emission level" means the magnitude of emission from a laser product of laser or collateral radiation of a wavelength and emission duration to which human access is possible as measured pursuant to paragraph (e) of this section.

(2) "Accessible emission limit" means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) "Aperture" means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) "Class I laser product" means any laser product which does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any emission duration.

(6) "Class II laser product" means any laser product which:

(i) Permits human access to laser radiation in excess of the accessible emission limits of Class I but not in excess of the accessible emission limits of Class II in the wavelength range of greater than 400 nanometers (nm) but less than or equal to 700 nm for emission durations greater than 0.25 second; and,

(ii) Does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(7) "Class III laser product" means any laser product which permits human access to laser radiation in excess of the accessible emission limits of Class I and Class II as applicable, but which does not permit human access to laser radiation in excess of the accessible emission limits of Class III for any emission duration.

(8) "Class IV laser product" means any laser product which permits human access to laser radiation in excess of the accessible emission limits of Class III.

(9) "Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of or necessary for the operation of a laser incorporated into that product.

(10) "Demonstration laser product" means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display or artistic composition. The term "demonstration laser product" does not apply to laser products which are designed and intended exclusively for other applications though they may be used for demonstration of those applications.

(11) "Emission duration" means the temporal duration of a pulse, of a series of pulses, or of continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance or servicing of a laser product.

(12) "Human access" means access at a particular point to laser or collateral radiation by any part of the human body, by a straight object having a useful length of 100 centimeters, or by any other object having a useful length of 10 centimeters, when laser or collateral radiation is incident at that point.

(13) "Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($J\ cm^{-2}\ sr^{-1}$).

(14) "Irradiance" means the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimer centimeter ($W\ cm^{-2}$).

(15) "Laser" means any device which can be made to produce or amplify electromagnetic radiation in the wavelength range of greater than 250 nm but less than or equal to 13,000 nm primarily by the process of controlled stimulated emission.

(16) "Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

(17) "Laser product" means any product or assemblage of components which constitutes, incorporates or is intended to incorporate a laser or laser system, and which is not sold to another manufacturer for use as a component (or replacement for such component) of an electronic product.

(18) "Laser radiation" means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(15) of this section which is produced as a result of controlled stimulated emission, or which is detectable with radiation so produced within the appropriate aperture stop specified in paragraph (e) of this section.

(19) "Laser system" means a laser in combination with an appropriate laser energy source with or without additional incorporated components.

(20) "Maintenance" means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b) (23) and (34) of this section.

(21) "Maximum output" means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of the total accessible laser radiation emitted in all directions by a laser product over the full range of operational capability at any time after manufacture.

(22) "Medical laser product" means any laser product manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical, or therapeutic laser or collateral irradiation of any part of the human body.

(23) "Operation" means the performance of the laser product over the full range of its intended functions. It does not include maintenance or service as defined in paragraph (b)(20) and (34) of this section.

(24) "Protective housing" means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in § 1040.11.

(25) "Pulse duration" means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(26) "Radiance" means radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($W\ cm^{-2}\ sr^{-1}$).

(27) "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(28) "Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter ($J\ cm^{-2}$).

(29) "Radiant power" means power emitted, transferred or received in the form of radiation, expressed in watts (W).

(30) "Remote control connector" means an electrical connector which permits the connection of external controls placed apart from other components of the laser product to prevent human access to all laser and collateral radiation in excess of the limits specified in this section and in § 1040.11.

(31) "Safety interlock" means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(32) "Sampling interval" means the magnitude of the time interval during which the level of accessible laser or collateral radiation is determined by a measurement process. The sampling interval is represented by the symbol (t), expressed in seconds.

(33) "Scanned laser radiation" means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(34) "Service" means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which §§ 1040.10 and 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraph (b)(20) and (23) of this section.

(35) "Surveying, leveling, or alignment laser product" means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(36) "Warning logotype" means a logotype as illustrated in either Figure 1 or Figure 2 of paragraph (g) of this section.

(37) "Wavelength" means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser products*—(1) *All laser products.* Each laser product shall be classified in accordance with definitions set forth in paragraph (b)(5) through (8) of this section on the basis of that combination of emission level(s), emission duration(s), and wavelength(s) of accessible laser radiation emitted over the full range of operational capability which results, at any time after manufacture, in the highest class specified in Tables I–A, I–B, and I–C of paragraph (d) of this section pursuant to paragraphs (d) and (e) of this section. For purposes of classification, Class II is higher than Class I, Class III is higher than Class II, and Class IV is higher than Class III.

(2) *Removable laser systems.* Any laser system which is incorporated into a laser product and is capable without modification of producing laser radiation when removed from the laser product, shall be considered a laser product and shall be separately subject to the applicable requirements for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation in each class are specified in Tables I–A, I–B and I–C of this paragraph in terms of the factors, k_1 and k_2, for different ranges of wavelength and emission duration. These factors are given in Table II–A of this paragraph, with selected numerical values in Table II–B of this paragraph, for various subranges of wavelength and emission duration. The accessible emission limits in Tables I–A, I–B and I–C of this paragraph are also expressed in terms of the sampling interval (t) for some emission duration intervals; and the correction factors in Table II–A of this paragraph are expressed in terms of the specific wavelength (λ) and sampling interval (t) for some subranges of wavelength and subintervals of emission duration. Accessible emission limits for collateral radiation are specified in Table III of this paragraph.

Notes applicable to Tables I–A, I–B and I–C:

(1) The quantities presented in the Tables are radiant energy expressed in joules (J); radiant exposure expressed in joules per square centimeter ($J\ cm^{-2}$); and integrated radiance expressed in joules per square centimeter per steradian ($J\ cm^{-2}\ sr^{-1}$).

(2) The factors k_1 and k_2 are wavelength dependent correction factors determined from Table II–A.

(3) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

(4) An accessible emission limit containing the units of joules, when divided by the sampling interval (t), is equivalent to an accessible emission limit containing the units of watts.

TABLE I–A

CLASS I ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration interval (seconds)	Class I – Accessible emission limits
>250 but ≤400	$\leq 3.0 \times 10^{4}$	$2.4 \times 10^{-5} k_1 k_2$ J*
	$> 3.0 \times 10^{4}$	$8.0 \times 10^{-10} k_1 k_2 t$ J
>400 but ≤1400	$> 1.0 \times 10^{-9}$ to 2.0×10^{-5}	$2.0 \times 10^{-7} k_1 k_2$ J
	$> 2.0 \times 10^{-5}$ to 1.0×10^{1}	$7.0 \times 10^{-4} k_1 k_2 t^{3/4}$ J
	$> 1.0 \times 10^{1}$ to 1.0×10^{4}	$3.9 \times 10^{-3} k_1 k_2$ J
	$> 1.0 \times 10^{4}$	$3.9 \times 10^{-7} k_1 k_2 t$ J
	OR**	
	$> 1.0 \times 10^{-9}$ to 1.0×10^{1}	$10 k_1 k_2 t^{1/3}$ J cm^{-2} sr^{-1}
	$> 1.0 \times 10^{1}$ to 1.0×10^{4}	$20 k_1 k_2$ J cm^{-2} sr^{-1}
	$> 1.0 \times 10^{4}$	$2.0 \times 10^{-3} k_1 k_2 t$ J cm^{-2} sr^{-1}
>1400 but ≤13000	$> 1.0 \times 10^{-9}$ to 1.0×10^{-7}	$7.9 \times 10^{-5} k_1 k_2$ J
	$> 1.0 \times 10^{-7}$ to 1.0×10^{1}	$4.4 \times 10^{-3} k_1 k_2 t^{1/4}$ J
	$> 1.0 \times 10^{1}$	$7.9 \times 10^{-4} k_1 k_2 t$ J

* Class I accessible emission limits for the wavelength range of greater than 250 nm but less than or equal to 400 nm shall not exceed the Class I accessible emission limits for the wavelength range of greater than 1400 nm but less than or equal to 13000 nm with a k_1 and k_2 of 1.0 for comparable sampling intervals.

**Instructions for the Class I dual limits are set forth in paragraph (d)(4) of this section.

TABLE I–B

CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration interval (seconds)	Class II – Accessible emission limits
>400 but ≤ 700	$>2.5 \times 10^{-1}$	$1.0 \times 10^{-3} k_1 k_2 t$ J

TABLE I–C

CLASS III ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration interval (seconds)	Class III – Accessible emission limits
>250 but ≤ 400	$\leq 2.5 \times 10^{-1}$	$3.8 \times 10^{-4} k_1 k_2$ J
	$>2.5 \times 10^{-1}$	$1.5 \times 10^{-3} k_1 k_2 t$ J
>400 but ≤ 1400	$>1.0 \times 10^{-9}$ to 2.5×10^{-1}	$10 k_1 k_2 t^{1/3}$ J cm^{-2} to a maximum value of 10 J cm^{-2}
	$>2.5 \times 10^{-1}$	$5.0 \times 10^{-1} t$ J
>1400 but ≤ 13000	$>1.0 \times 10^{-9}$ to 1.0×10^{1}	10 J cm^{-2}
	$>1.0 \times 10^{1}$	$5.0 \times 10^{-1} t$ J

TABLE II–A

VALUES OF WAVELENGTH DEPENDENT CORRECTION FACTORS k_1 AND k_2

Wavelength band (nanometers)	k_1	k_2		
250 to 302.4	1.0	1.0		
> 302.4 to 315	$10^{\left[\frac{\lambda - 302.4}{5}\right]}$	1.0		
> 315 to 400	330.0	1.0		
> 400 to 700	1.0	1.0		
> 700 to 800	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq \frac{10100}{\lambda - 699}$ then: $k_2 = 1.0$	if: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{t(\lambda - 699)}{10100}$	if: $t > 10^4$ then: $k_2 = \frac{\lambda - 699}{1.01}$
> 800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq 100$ then: $k_2 = 1.0$	if: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$	if: $t > 10^4$ then: $k_2 = 100$
> 1060 to 1400	5.0			
> 1400 to 1535	1.0	1.0		
> 1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$	1.0		
	$t > 10^{-7}$ $k_1 = 1.0$			
> 1545 to 13000	1.0	1.0		

Note: The variables in the expressions are the magnitudes of the sampling interval (t), in units of seconds, and the wavelength (λ), in units of nanometers.

TABLE II–B

SELECTED NUMERICAL SOLUTIONS FOR k_1 AND k_2

Wavelength (nanometers)	k_1	k_2				
		$t \leq 100$	$t = 300$	$t = 1000$	$t = 3000$	$t \geq 10{,}000$
250	1.0	1.0				
300	1.0					
302	1.0					
303	1.32					
304	2.09					
305	3.31					
306	5.25					
307	8.32					
308	13.2					
309	20.9					
310	33.1					
311	52.5					
312	83.2					
313	132.0					
314	209.0					
315	330.0					
400	330.0					
401	1.0					
500	1.0					
600	1.0					
700	1.0					
710	1.05	1	1	1.1	3.3	11.0
720	1.09	1	1	2.1	6.3	21.0
730	1.14	1	1	3.1	9.3	31.0
740	1.20	1	1.2	4.1	12.0	41.0
750	1.25	1	1.5	5.0	15.0	50.0
760	1.31	1	1.8	6.0	18.0	60.0
770	1.37	1	2.1	7.0	21.0	70.0
780	1.43	1	2.4	8.0	24.0	80.0
790	1.50	1	2.7	9.0	27.0	90.0
800	1.56	1	3.0	10.0	30.0	100.0
850	1.95	1	3.0	10.0	30.0	100.0
900	2.44	1	3.0	10.0	30.0	100.0
950	3.05	1	3.0	10.0	30.0	100.0
1000	3.82	1	3.0	10.0	30.0	100.0
1050	4.78	1	3.0	10.0	30.0	100.0
1060	5.00	1	3.0	10.0	30.0	100.0
1100	5.00	1	3.0	10.0	30.0	100.0
1400	5.00	1	3.0	10.0	30.0	100.0
1500	1.0	1.0				
1540	100.0*					
1600	1.0					
13000	1.0					

*The factor $k_1 = 100.0$ when $t \leq 10^{-7}$, and $k_1 = 1.0$ when $t > 10^{-7}$

Note: The variable (t) is the magnitude of the sampling interval in units of seconds.

TABLE III

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL RADIATION FROM LASER PRODUCTS

1. *Accessible emission limits* for collateral radiation having wavelengths greater than 250 nm but less than or equal to 13,000 nm are identical to the accessible emission limits of Class I laser radiation as determined from Tables I–A and II–A set forth in this paragraph for the appropriate wavelength(s) and emission duration interval.

2. *Accessible emission limit* for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.

(1) *Beam of a single wavelength.* Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the emission duration intervals specified in Tables I–A, I–B and I–C of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation, having two or more wavelengths within any one of the wavelength ranges specified in Tables I–A, I–B and I–C of this paragraph, exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables I–A, I–B and I–C of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d)(1) or (2) of this section.

(4) *Class I dual limits.* Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1,400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any corresponding emission duration interval specified in Table I–A of this paragraph; and,

(ii) The Class I accessible emission limits for integrated radiance within any corresponding emission duration interval specified in Table I–A of this paragraph.

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Because compliance is required for the useful life of a product, such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Tests for compliance with each of the applicable requirements of this section and § 1040.11 shall be made:

(i) Under those operational conditions and procedures which maximize the accessible emission levels including start-up, stabilized operation, and shut-down of the laser product; and,

(ii) With all controls and adjustments listed in the operation, maintenance and service instructions adjusted for the maximum accessible emission level of radiation which is not expected to be detrimental to the functional integrity of the product; and,

(iii) At points in space to which human access is possible in the product configuration during operation, maintenance or service which is necessary to determine compliance with each requirement, e.g., if operation may include removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and,

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and,

(v) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) The radiant power (W) or radiant energy (J) detectable within a circular aperture stop having a diameter of 80 millimeters (except for scanned laser radiation).

(ii) The irradiance ($W\ cm^{-2}$) or radiant exposure ($J\ cm^{-2}$) averaged over a circular aperture stop having a diameter of 7 millimeters.

(iii) The radiance ($W\ cm^{-2}\ sr^{-1}$) or integrated radiance ($J\ cm^{-2}\ sr^{-1}$) which is equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within an effective solid angle of acceptance of 10^{-5} sr, divided by that solid angle (sr) and by the area of the aperture stop (cm^2).

(4) *Measurement parameters for scanned laser radiation.* Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable within a stationary circular aperture stop having a 7-millimeter diameter. The resulting temporal variation of detected radiation shall be considered as a pulse or series of pulses.

(f) *Operational requirements*—(1) *Protective housing.* Each laser product, regardless of its class, shall have a protective housing which, when in place, prevents human access during operation to:

(i) Laser radiation in excess of the accessible emission limits of Class I wherever and whenever human access to laser radiation exceeding the limits of Class I is not necessary for the performance of the intended function(s) of the product; and,

(ii) Laser radiation in excess of the accessible emission limits of Class II wherever and whenever human access to laser radiation exceeding the limits of Class II is not necessary for the performance of the intended function(s) of the product; and,

(iii) Laser radiation in excess of the accessible emission limits of Class III wherever and whenever human access to laser radiation exceeding the limits of Class III is not necessary for the performance of the intended function(s) of the product; and,

(iv) Collateral radiation in excess of the accessible emission limits specified in Table III in paragraph (d) of this section wherever and whenever human access to collateral radiation in excess of those limits is not necessary for the performance of the intended function(s) of the product.

(2) *Safety interlocks.* (i) Each laser product, regardless of its class, shall be provided with a safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of such portion of the protective housing could permit human access to laser or collateral radiation in excess of the accessible emission limits applicable under paragraph (f)(1) of this section. Each required safety interlock, unless defeated, shall:

(*a*) Prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing; and,

(*b*) Preclude removal or displacement of such portion of the protective housing upon failure to prevent human access to laser and collateral radiation as required in paragraph (f)(2)(i)(*a*) of this section.

(ii) Laser products which incorporate required safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(iii) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) *Remote control connector.* Each laser system classified as a Class III or IV laser product shall incorporate a

readily accessible remote control connector having an electrical potential difference on the remote control connector no greater than 130 root-mean-square volts. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section shall be prevented.

(4) *Key control.* Each laser system classified as a Class III or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator.* Each laser system classified as a Class II, III, or IV laser product shall provide a visible or audible indication immediately before and during the emission of accessible laser radiation in excess of the limits of Class I. Any visual indicator shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate visual or aural indicators as described. The visual indicators shall be positioned so that viewing does not require human access to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III.

(6) *Beam attenuator.* Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors or the key-actuated master control, capable of preventing human access to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table III.

(7) *Location of controls.* Each Class II, III, or IV laser product shall have operational and adjustment controls located so that human access to laser and collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section is unnecessary for operation or adjustment of controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall attenuate at all times the accessible levels of transmitted laser and collateral radiation to less than the accessible emission limits of Class I and Table III of paragraph (d) of this section. For any shutter or variable attenuator incorporated into such viewing optics, viewpoints, or display screens, a means shall be provided:

(i) To prevent human access to laser and collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section whenever the shutter is opened or the attenuator varied; and,

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when human access is possible to transmitted laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section.

(9) *Scanning safeguard.* Laser products which emit accessible scanned laser radiation shall not, as a result of scan failure or other failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limit(s) which are applicable to the scanned laser radiation when the product is functioning as intended.

(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3 of this chapter, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class II designation and warning.* Each Class II laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

(Position 1 on the logotype)
"LASER RADIATION—DO NOT STARE INTO BEAM"; and,
(Position 3 on the logotype)
"CLASS II LASER PRODUCT".

WARNING LOGOTYPE A

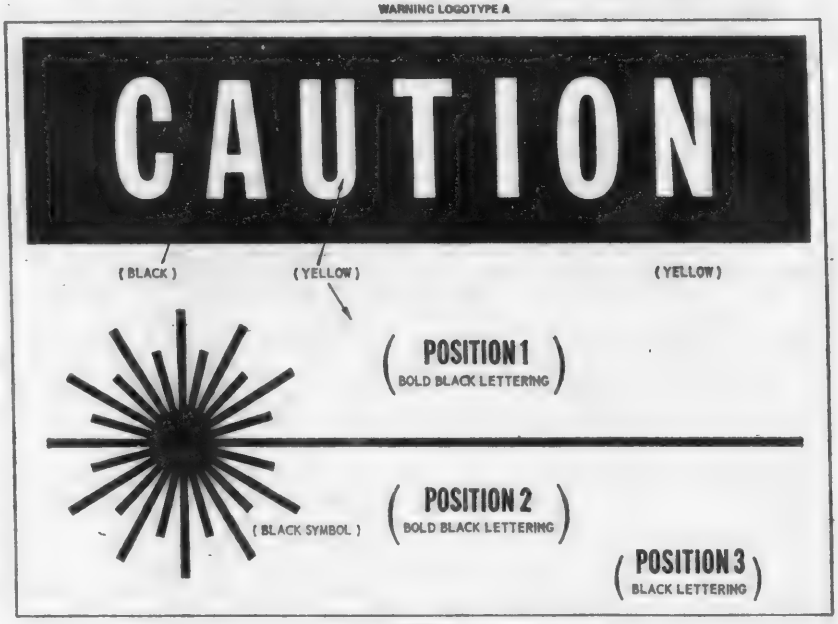

FIGURE 1

(2) *Class III designation and warning.* (i) Each laser product classified in Class III solely because of the emission of accessible laser radiation for emission durations greater than 3.8×10^{-4} second and in the wavelength range of greater than 400 nm but less than or equal to 700 nm, with an irradiance of less than or equal to 2.5×10^{-3} W cm^{-2} and with a peak radiant power of less than or equal to 5.0×10^{-3} W shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1) of this section) and including the following wording:

(Position 1 on the logotype)
"LASER RADIATION—DO NOT STARE INTO THE BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and,
(Position 3 on the logotype)
"CLASS III LASER PRODUCT".

(ii) Each Class III laser product other than those described in paragraph (g)(2)(i) of this section shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:

(Position 1 on the logotype)
"LASER RADIATION—AVOID EXPOSURE TO BEAM"; and,
(Position 3 on the logotype)
"CLASS III LASER PRODUCT".

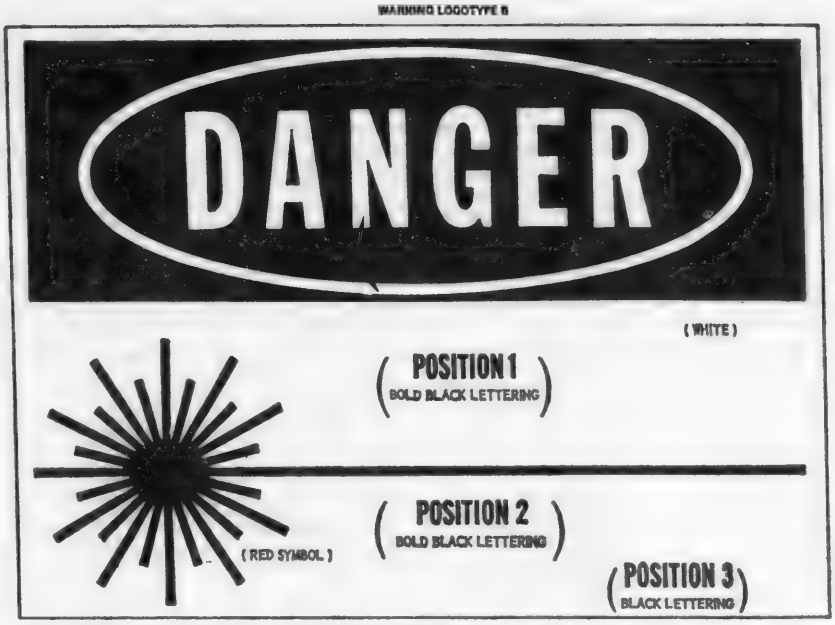

FIGURE 2

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g) (2) (ii) of this section), and including the following wording:

(Position 1 on the logotype)
"LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; and,
(Position 3 on the logotype)
"CLASS IV LASER PRODUCT".

(4) *Aperture label.* Each laser product, except medical laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section, a label(s) bearing the following wording: "AVOID EXPOSURE—Radiation is emitted from this aperture."

(5) *Radiation output information.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing having no safety interlock, which is designed to be displaced or removed during operation, maintenance or servicing, and which thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and Table III in paragraph (d) of this section. Such labels shall be visible on the protective housing prior to displacement or removal of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nm but less than or equal to 700 nm; and,

(*b*) Not in excess of the accessible emission limits of Class II; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of wavelength(s) and emission duration(s).

(ii) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class II; and,

(*b*) In excess of neither an irradiance of 2.5×10^{-3} W cm^{-2} nor a peak power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of wavelength(s) and emission duration(s).

(iii) "DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for accessible laser radiation:

(*a*) Not in excess of the accessible emission limits of Class III for all wavelengths; and either,

(*b*) In excess of either an irradiance of 2.5×10^{-3} W cm^{-2} or a peak power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; or,

(*c*) In excess of the accessible emission limit of Class I for any other wavelength.

(iv) "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for accessible laser radiation in excess of the accessible emission limits of Class III for all wavelengths.

(v) "CAUTION—Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table III, item 1 of paragraph (d) of this section.

(vi) "CAUTION—Hazardous x-ray radiation when open." for collateral radiation in excess of the accessible emission limits in Table III, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked protective housing which is designed to be displaced or removed during operation, maintenance or servicing, and which thereby could permit human access to laser or collateral radiation in excess of the limits of Class I or Table III in paragraph (d) of this section. Such labels shall be visible on the protective housing prior to displacement or removal of the protective housing and visible on the product in close proximity to the opening created by the removal or displacement of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nm but less than or equal to 700 nm; and,

(*b*) Not in excess of the accessible emission limits of Class II; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of wavelength(s) and emission duration(s).

(ii) "CAUTION — Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class II; and,

(*b*) In excess of neither an irradiance of 2.5×10^{-3} W cm^{-2} nor a peak power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of wavelength(s) and emission duration(s).

(iii) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM." for accessible laser radiation:

(*a*) Not in excess of the accessible emission limits of Class III for all wavelengths; and either,

(*b*) In excess of either an irradiance of 2.5×10^{-3} W cm^{-2} or a peak power of 5.0×10^{-3} W for emission durations

greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; or,

(c) In excess of the accessible emission limit of Class I for any other wavelength.

(iv) "DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for accessible laser radiation in excess of the accessible emission limits of Class III for all wavelengths.

(v) "CAUTION—Hazardous electromagnetic radiation when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table III, item 1 of paragraph (d) of this section.

(vi) "CAUTION — Hazardous x-ray radiation when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table III, item 2 of paragraph (d) of this section.

(8) *Warning for invisible radiation.* On the labels specified in this paragraph and § 1040.11, if the wavelength(s) of the laser or collateral radiation referred to is:

(i) Less than or equal to 400 nm or greater than 700 nm, the word "invisible" shall appropriately precede the word "radiation"; or,

(ii) In the range specified in paragraph (g)(8)(i) of this section and also within the range of greater than 400 nm but less than or equal to 700 nm, the words "visible and invisible" shall appropriately precede the word "radiation".

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human access to laser and collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this paragraph and § 1040.11 shall be permanently affixed to the laser product, legible, and clearly visible during operation, maintenance or service as appropriate. If the size, configuration, or design of the laser product would preclude compliance with the requirements for any required label, the Director, Bureau of Radiological Health, may approve alternate means of providing such label(s).

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for proper assembly and safe use including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I–A, I–B, I–C and III of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement in appropriate units of pulse duration(s) and maximum output, with the magnitudes of the cumulative measurement uncertainty and any expected increase in the measured quantities at any time after manufacture added to the values measured at the time of manufacture (duration of pulses resulting from unintentional mode-locking need not be specified; however, those conditions associated with the product known to result in unintentional mode-locking shall be specified).

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 or 2 of paragraph (g)(1) and (2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of controls, adjustments and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."

(v) In the case of laser products other than laser systems, a statement of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the warning logotype required to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 or 2 under paragraph (g)(1) and (2)(ii) of this section).

(ii) To servicing dealers and distributors, and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model including clear warnings and precautions to be taken to avoid possible exposure to radiation and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and, in all such service instructions a listing of those controls and procedures which could be utilized by persons other than the manufacturer or his agents to increase accessible emission levels of radiation, and a clear description of the location of displaceable portions of the protective housing which could allow access to laser or collateral radiation in excess of the accessible emission limits in Tables I–A, I–B, I–C and III of paragraph (d) of this section. The instructions shall include protective procedures for service personnel, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified pursuant to § 1010.2 of this chapter, by any person engaged in the business of manufacturing, assembling or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) On Class III or IV laser products, incorporate in each medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body with an error in measurement of no more than ±20 percent when calibrated in accordance with paragraph (a)(2) of this section. Indication of the measurement shall be in International System Units.

(2) Supply with each medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a)(1) of this section.

(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of § 1040.10(d), a label bearing the wording: "Radiation is emitted from this aperture."

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, Class II, or Class III laser product and, in addition:

(1) Shall not permit human access to laser radiation in the wavelength range of greater than 400 nm but less than or equal to 700 nm with a peak radiant power that exceeds 5×10^{-3} W for any sampling interval greater than 3.8×10^{-4} second; and,

(2) Shall not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I or Class II laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and Class II as applicable.

Interested persons may, on or before October 4, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: August 19, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74–19655 Filed 9–3–74;8:45 am]

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